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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/813,352	03/21/2001	Luis Lopez-Molina	2312-109	3472

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COLLINS, CYNTHIA E

ART UNIT	PAPER NUMBER
1638	11

DATE MAILED: 06/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application N .	Applicant(s)	
Office Action Summary	09/813,352	LOPEZ-MOLINA ET AL.	
	Examiner	**Art Unit**	
	Cynthia Collins	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Peri d for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 March 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) *1-24 and 32-36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *9* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The Amendment filed March 24, 2003, paper no.10, has been entered.

Claims 25, 30 and 31 are newly amended.

Claims 1-36 are pending.

Claims 1-24 and 32-36 are withdrawn from consideration.

Claims 25-31 are examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All previous objections and rejections not set forth below have been withdrawn.

Information Disclosure Statement

An initialed and dated copy of Applicant's IDS form 1449, filed December 18, 2002, Paper No. 9, is attached to the instant Office action.

Claim Rejections - 35 USC § 112

Claims 30-31 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a seed, seedling or plant that is transgenic for an *ABI5* polynucleotide and that overproduces the encoded ABI5 polypeptide and that exhibits increased sensitivity to abscisic acid induced inhibition of seed germination and root growth relative to nontransformed plants, does not reasonably provide enablement for a seed, seedling or plant that is transgenic for an *ABI5* polynucleotide that overproduces the encoded ABI5 polypeptide and

that is tolerant to drought stress or salt stress, for the reasons of record set forth in the office action mailed October 22, 2002.

Applicant's arguments filed March 24, 2003, have been fully considered but they are not persuasive.

Applicant argues that the Office has provided no evidence or reasoning to rebut the presumptive accuracy of the disclosure, and that the specification provides sufficient detail for one skilled in the art to identify ABI5 sequences for use in the claimed invention. Applicant points out that the specification directly refers to the role of ABA in plant stress responses, and that the specification provides experimental evidence demonstrating that ABA regulates ABI5 accumulation, that ABI5 is induced by drought and high salt stress, and that transgenic plants overexpressing ABI5 are hypersensitive to ABA with respect to both germination and vegetative growth, as well as resistant to drought (reply pages 7-8).

Applicant further points out that all of the methods required to identify ABI5 genes, to transfect plants to overproduce ABI5, and to assay their resistance to drought and salt stress are set forth in the specification. Applicant further that argues that the actual reduction to practice of one embodiment of a seed transgenic for ABI5 is sufficient to enable all of the claimed embodiments, and that it would not require undue experimentation to practice additional embodiments (reply page 8). Applicant further argues that the Office is speculative in asserting that it would require undue experimentation to practice the claimed invention, and that the mere assertion of unpredictability is not sufficient to establish a lack of enablement (reply pages 8-9).

With respect to the presumptive accuracy of the disclosure, the prior office action set forth at page 5 that the ability of a polynucleotide to confer drought or high salt resistance to transgenic seed, seedlings or plants is unpredictable, and that, for example, it may not be possible to confer drought or stress resistance on a transgenic plant by overproducing ABI5 if ABI5 is not directly or indirectly involved in mediating drought or high salt resistance. The prior office action set forth at page 5 that alternatively, it may be necessary to express ABI5 at a certain time in plant development, or in a particular tissue or tissues, in order to confer drought or stress resistance on a transgenic plant.

With respect to the role of ABA in plant stress responses, the Office does not dispute the assertion that ABA is known to play a role in plant stress responses, but maintains that the observation that ABA is known to play a role in plant stress responses does not enable the claimed invention because it has not been established that the expression of ABI5 in a transgenic plant produces the same effect as the treatment of a plant with exogenous ABA. That expression of ABI5 in a transgenic plant would produce the same effect as the treatment of a plant with exogenous ABA is unpredictable as ABA effects are known to be concentration dependent. For example, Himmelbach et al. teach that the effect of ABA on root growth is concentration dependent (Phil. Trans. R. Soc. Lond. B, 1998, Vol. 353, pages 1439-1444, Applicant's IDS, see page 1439 column 2 last paragraph through page 1439 column1 last full paragraph). Additionally, for example, Koornneef et al. teach that different abscisic acid-insensitive mutants of *Arabidopsis* exhibit different levels of sensitivity to exogenous ABA (Physiol. Plant., 1984, Vol. 61, pages 377-383, Applicant's IDS, see page 380 Figures 3 and 4).

With respect to ABA regulation of ABI5 accumulation and the induction of ABI5 by drought and high salt stress, the Office does not dispute these observations, but the Office maintains that a correlation between ABI5 accumulation and ABA treatment or drought or high salt stress treatment does not enable the claimed invention because it has not been established that the accumulation of ABI5 in a transgenic plant confers drought or salt stress tolerance. That the accumulation of ABI5 in a transgenic plant would confer drought or salt stress tolerance is unpredictable as the correlation between a stress response and stress tolerance is not always indicative of a cause and effect relationship.

With respect to the experimental evidence provided in the specification, the Office does not dispute that transgenic plants overexpressing an *ABI5* polynucleotide obtained from *Arabidopsis* (GenBank Accession AC006921) exhibit increased sensitivity to abscisic acid induced inhibition of seed germination and root growth relative to nontransformed *Arabidopsis* plants, as was previously reflected in the scope of the enablement rejection. However, the Office finds no evidence at page 14 of the specification that transgenic plants overexpressing ABI5 are tolerant to drought. The experimental evidence at page 14 of the specification indicates only that ABA-treated wild type seeds are more tolerant to drought stress than are ABA-treated *abi5-4* mutant seed.

With respect to the identification of ABI5 sequences for use in the claimed invention, the enablement rejection has been modified accordingly.

The Office also disagrees that the actual reduction to practice of one embodiment of a seed transgenic for ABI5 is sufficient to enable all of the claimed embodiments, because the ability of a polynucleotide to confer drought or high salt tolerance to transgenic seed, seedlings

or plants is unpredictable, such that it would require undue experimentation to determine how to express ABI5 in a manner that would confer drought or salt stress tolerance. The Office further disagrees that its assertion that it would require undue experimentation to practice the claimed invention is speculative, as the Office has set forth reasons as to why undue experimentation would be required to practice the claimed invention, , as discussed *supra*.

Claims 25-28 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "ABI5", for the reasons of record set forth in the office action mailed October 22, 2002.

Applicant's arguments filed March 24, 2003, have been fully considered but they are not persuasive.

Applicant points to page 1 of the specification where the definition of the acronym "ABI5" is defined, and argues that the use of "ABI5" in the claims is not indefinite (reply page 10).

The Office maintains that the definition of "ABI5" set forth in the specification does not limit the rejected claims. It is suggested that independent claim 25 be amended to recite "abscisic acid insensitive" in order to clarify the meaning of the acronym "ABI5".

Claims 25-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "gene" or "transgene", for the reasons of record set forth in the office action mailed October 22, 2002.

Applicant's arguments filed March 24, 2003, have been fully considered but they are not persuasive.

Applicant argues that the word "gene" is as definite as the subject matter permits, and that limiting the claims to isolated sequences unduly limits the scope of the claims. Applicants point out that it is possible to transpose genes already within a plant's genome to other locations, as well as to activate endogenous genes by the insertion of an activator or promoter (reply page 10).

The Office maintains that the disclosed invention utilizes isolated sequences only, and that the disclosed invention does not utilize gene transposition and gene activation. Furthermore, the Office interprets "gene" as having regulatory sequences, coding and noncoding sequences, and termination sequences. This does not appear to be applicant's invention. It is suggested that the claims be amended to recite "polynucleotide encoding" rather than "gene" or "transgene".

Claim 27 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "activatable", for the reasons of record set forth in the office action mailed October 22, 2002.

Applicant's arguments filed March 24, 2003, have been fully considered but they are not persuasive.

In response to the rejection, Applicant points to page 7 of the specification where "activatable promoter" is defined (reply page 11).

The Office maintains that the definition of "activatable promoter" set forth in the specification does not limit the rejected claim, and that the use of "activatable promoter" in the

claim is indefinite due to the multiple ways in which "activatable" could be interpreted. It is unclear how an "activatable" promoter would be different from an inducible promoter, or from any functional promoter, as all promoters function via activation, directly or indirectly, by proteins or other regulatory molecules.

Claim 28 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "overproduces", for the reasons of record set forth in the office action mailed October 22, 2002.

Claim 29 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "hypersensitive", for the reasons of record set forth in the office action mailed October 22, 2002.

Applicant's arguments filed March 24, 2003, have been fully considered but they are not persuasive.

In response to the rejection, Applicant points to pages 7-8 of the specification where "overproduces" and "hypersensitive" are defined (reply page 11).

The Office maintains that the definitions of "overproduces" and "hypersensitive" set forth in the specification do not limit the rejected claims, and that the use of "overproduces" and "hypersensitive" in the claims is indefinite due to the lack of a comparative basis for the terms.

Claim 31 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "high", for the reasons of record set forth in the office action mailed October 22, 2002.

Applicant's arguments filed March 24, 2003, have been fully considered but they are not persuasive.

In response to the rejection, Applicant points to page 7 of the specification where "high salt" is defined (reply page 11).

The Office maintains that the definition of "high salt" set forth in the specification does not limit the rejected claim, and that the use of "high salt" in the claim is indefinite due to the lack of a comparative basis for the term.

Claims 30 and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "tolerant", as "tolerant" is a relative term that lacks a comparative basis.

Applicant's arguments filed March 24, 2003, in response to the rejection of claims 30 and 31 as being indefinite in the recitation of "resistant" have been fully considered but they are not persuasive.

In response to the previous rejection, Applicant points to page 7 of the specification where "tolerant" is defined (reply page 11).

The Office maintains that the definition of "tolerant" set forth in the specification does not limit the rejected claims, and that the use of "tolerant" in the claim is indefinite due to the lack of a comparative basis for the term. It is suggested that the claims be amended to indicate that the plants are tolerant when compared to untransformed plants.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 25 and 27-31 are rejected under 35 U.S.C. 102(a) as being anticipated by Finkelstein et al. (The Plant Cell, April 2000, Vol. 12, pages 599-609, Applicant's IDS).

The claims are drawn to a seed, seedling or plant expressing an ABI5 transgene, including a seed, seedling or plant expressing an ABI5 gene under the control of an activatable promoter, a seed, seedling or plant that overproduces ABI5, a seed, seedling or plant that is hypersensitive to abscisic acid, a seed, seedling or plant that is drought tolerant, and a seed, seedling or plant that is tolerant to high salt.

Finkelstein et al. teach transgenic *Arabidopsis* plants that express an ABI5 transgene (page 600 column 2 second full paragraph; page 601 Table 1). The transgenic plants taught by Finkelstein et al. express an ABI5 gene under the control of an activatable promoter as any functional promoter is by definition activatable by native proteins that regulate its activity. The transgenic plants taught by Finkelstein et al. also overproduce ABI5 relative to the nontransformed *abi5* mutant plants. The transgenic plants taught by Finkelstein et al. would inherently be hypersensitive to abscisic acid and tolerant to drought and high salt as the claims require only that the plant express an ABI5 transgene.

Claims 25 and 27-31 are rejected under 35 U.S.C. 102(a) as being anticipated by Lopez-Molina et al. (Plant Cell Physiol. May 2000, Vol. 41, No. 5, pages 541-547, Applicant's IDS).

The claims are drawn to a seed, seedling or plant expressing an ABI5 transgene, including a seed, seedling or plant expressing an ABI5 gene under the control of an activatable promoter, a seed, seedling or plant that overproduces ABI5, a seed, seedling or plant that is hypersensitive to abscisic acid, a seed, seedling or plant that is drought tolerant, and a seed, seedling or plant that is tolerant to high salt.

Lopez-Molina et al. teach transgenic *Arabidopsis* plants that express an ABI5 transgene (page 543 Table 1; page 545 column 1 first full paragraph). The transgenic plants taught by Lopez-Molina et al. express an ABI5 gene under the control of an activatable promoter as any functional promoter is by definition activatable by native proteins that regulate its activity. The transgenic plants taught by Lopez-Molina et al. also overproduce ABI5 relative to the nontransformed *abi5* mutant plants. The transgenic plants taught by Lopez-Molina et al. would inherently be hypersensitive to abscisic acid and tolerant to drought and high salt as the claims require only that the plant express an ABI5 transgene.

Remarks

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC
June 13, 2003

PHUONG T. BUI
PRIMARY EXAMINER